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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,371	09/30/2003	Don A. Tanaka	END5098-0515140	5198
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FROST BROWN TODD, LLC			EXAMINER	
2200 PNC CENTER			RYCKMAN, MELISSA K	
201 E. FIFTH STREET				
CINCINNATI, OH 45202			ART UNIT	PAPER NUMBER
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			06/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com  
rgaunce@fbtlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/674,371	<b>Applicant(s)</b> TANAKA ET AL.
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 January 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 10,15,17,19 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10,15,17,19 and 25-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is in response to claims and arguments received on 1/14/08.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the unattached end of each loop is positioned adjacent to another portion of the loop to shield the unattached end from tissue contact (claim 25) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant has not disclosed "the unattached end of each loop is positioned adjacent to another portion of the loop to shield the unattached end from tissue contact".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 19, 23, 24, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Park (U.S. Pub. No. 2003/0120292).

Park teaches an anastomotic device (Fig. 1), comprising a slidingly woven tube, the woven tube woven from a continuous wire strand (20, Fig. 1), the woven tube defining a longitudinal axis (12, Fig. 1), and having each longitudinal end terminate in slidably engaging circumferential petals (20', Fig. 4F), the woven tube having an unactuated position (center, Fig. 4F) of a generally cylindrical shape and an actuated position (20', Fig. 4F) of a hollow rivet shape respectively for insertion through and for forming an anastomotic attachment defining a hollow opening between two proximate tissue walls at an anastomotic surgical site (Fig. 4F), wherein each petal (20') comprises a petal tip flaring directionally outward (20' flares away from center tissue) away from the tissue walls when the anastomotic device is in the actuated position, and as said anastomotic device moves from the unactuated to the actuated position, the direction of the flare reduces sliding friction between moving petals (Figs. 4D-4F), and when the anastomotic device is in the actuated position, the direction of the flare away from the tissue walls reduces pressure on tissue captured between the tip of each petal (Fig. 4G).

Claim 19:

Park teaches an underlying portion of each circumferential petal is shaped to diverge from an overlying portion of an adjacent petal for mitigating resistance to actuation (Fig. 3B).

Claim 23:

Park teaches the flaring of each circumferential petal tip comprises a monotonic slope toward a distal tip of the petal (Fig. 3B).

Claim 24:

Park teaches at least a portion of each petal has an uncurved section (portion is uncurved, Fig. 3B).

Claim 30:

Peterson teaches the wire has shape memory effect properties (para. 8).

***Claim Rejections - 35 USC § 103***

Claims 15,17,25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park (U.S. Pub. No. 2003/0120292) as applied to claim 10 above, and further in view of McNamara (U.S. Patent No. 6,004,347).

Claim 15:

Park teaches the claimed invention but does not include a strand, however McNamara teaches the woven tube comprises at least one strand (42, Fig. 6,7) having unattached ends (Fig. 6 and 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the one strand of McNamara in combination with the device of Park, as the strand helps to maintain the position of the device.

Claim 17:

Park teaches the claimed invention but does not have the unattached ends each terminate in a loop. However, McNamara teaches the unattached ends each terminate in a loop (Fig. 7, col. 7, ll. 25-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the McNamara ends to the device of Park, as the loops help to keep the tissue in position.

Claims 25 and 26:

Park teaches the claimed invention but does not teach the unattached end of each loop is positioned adjacent to another portion of the loop to shield the unattached end from tissue contact, however McNamara teaches a bent loop end that is flexible, therefore it is capable of being arranged as described in the claim (Fig. 7, col. 7, ll. 25-30) and McNamara teaches the anastomotic device is in the deployed position, the loops are orientated to position the unattached ends away from tissue contact.

It would have been obvious to one of ordinary skill in the art to arrange the loop as described in the claim to prevent damage to the surrounding tissue.

Claim 27:

Park teaches the claimed invention but does not teach the direction of the unattached ends as described, however McNamara teaches the unattached ends (40) are flared in the same direction (Fig. 2) as the petal tips (360).

It would have been obvious to one of ordinary skill in the art to have the unattached ends flare in the same direction as the petals as this provides more surface area to attach the base of the strand as shown in Fig. 6 in McNamara (points, 46 and 48 are attached to 36).

Claim 28:

Park teaches the claimed invention but does not have the unattached ends extend outside of the woven petals, however McNamara teaches the unattached ends (40) extend outside of the woven petals (Fig. 8).

It would have been obvious to one of ordinary skill in the art to have the unattached ends extend outside the woven petals as this helps the device maintain the position of the tissue.

Claim 29:

Park and McNamara teaches the anastomotic device is configured to operably engage with an anastomotic device applier (McNamara, Fig. 15) and the unattached ends are configured to avoid interference with the applier when moving the anastomotic device from the unactuated to the actuated position (Figs. 14-16).

#### ***Response to Arguments***

Applicant's arguments with respect to claims 10, 15, 17, 19 and 23-30 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR  
/Melissa Ryckman/  
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773